IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	CRIMINAL ACTION
	:	
v.	:	
	:	
MURTY VEPURI, et al.	:	NO. 21-132

MEMORANDUM

Bartle, J. February 23, 2022

The Government has filed a two-count superseding indictment against defendants KVK-Tech, Inc. ("KVK"), Murty Vepuri, and Ashvin Panchal.[1] It charges defendants with one count of conspiracy to defraud the United States under 18 U.S.C. § 371, and specifically alleges in paragraph 16 that defendants conspired:

> a. [to] defraud the United States and its agencies by impeding, impairing, and defeating the lawful functions of the FDA [Food & Drug Administration] to protect the health and safety of the public by ensuring that drugs marketed and distributed in the United States were safe and effective for their intended uses; and
>
> b. [to] commit an offense against the United States, by: (1) with the intent to defraud and mislead, introducing or delivering for introduction, and causing the introduction or delivery for introduction, into interstate commerce of unapproved drugs in violation of Title 21 United States Code,

1. On April 5, 2021, the Government filed an information charging Vepuri on one count of distributing new drugs without FDA approval in violation of 21 U.S.C. §§ 331(d), 333(a)(1). The Government then filed the superseding indictment on June 10, 2021.

> Sections 331(d) and 355(a); and
> (2) knowingly and willfully making materially false, fictitious, and fraudulent statements and representations, and falsifying and concealing material facts in a matter within the jurisdiction of the FDA, an agency of the executive branch of the United States, in violation of Title 18, United States Code, Section 1001.

KVK has also been indicted on a separate count for mail fraud and aiding and abetting under 18 U.S.C. §§ 1341, 2.

Before the court are the motions of KVK and Panchal to dismiss the superseding indictment for failure to state an offense (Docs. # 96, 102) pursuant to Rule 12(b)(3) of the Federal Rules of Criminal Procedure.[2] The court has entered orders allowing each defendant to join as movants in the pending motions.

I

When a defendant moves to dismiss an indictment for failure to state an offense, the court limits its review to the four corners of the indictment and accepts as true its factual allegations. United States v. Huet, 665 F.3d 588, 595-96 (3d Cir. 2012). The defendant may not at this stage challenge the sufficiency of the evidence. United States v. DeLaurentis, 230 F.3d 659, 660 (3d Cir. 2000). Rather, the defendant is limited

2. In his motion, Panchal also moves to dismiss the superseding indictment on statute of limitations grounds, which will be addressed in a separate Memorandum.

to demonstrating that the indictment on its face does not charge one or more essential elements of the offense. Huet, 665 F.3d at 595–96.

II

The Government has alleged the following facts. KVK is a generic drug manufacturer and distributor based in Newtown, Pennsylvania. Although Vepuri is not named in any of KVK's ownership documents, he is described as the company's de facto owner and operator. At all relevant times, Panchal was KVK's director of quality assurance.

In 2007, the Food & Drug Administration ("FDA") approved KVK's Abbreviated New Drug Application ("ANDA) to manufacture and distribute Hydroxyzine Hydrochloride ("Hydroxyzine"), a sedative drug for the treatment of anxiety and tension. As part of its approved ANDA, the FDA permitted KVK to produce the drug using an active pharmaceutical ingredient ("API"), hydroxyzine hydrochloride, manufactured only by UCB Pharma S.A. ("UCB") in its Belgian facility. In 2008, the FDA approved KVK's application to use the API produced by another manufacturer, Cosma, S.p.A. in Italy.

After an explosion at UCB's facility in 2010, UCB helped KVK purchase the API from a different source, Dr. Reddy's Laboratories ("DRL") in Mexico. Vepuri as KVK's agent authorized the purchase of this API. Panchal accepted shipments

of the API on KVK's behalf in January, March, and May 2011 and approved their use. KVK did not inform the FDA that it was manufacturing Hydroxyzine using the API from DRL. From April 2011 through December 2013, KVK manufactured and distributed over 300,000 bottles of Hydroxyzine using the DRL API.

Meanwhile in June 2011, the FDA issued a letter to DRL warning that it was committing violations of current Good Manufacturing Practices,[3] deeming "adulterated" all API that it produced at its Mexican facility and stating that "'approval of any new applications or supplements listing [DRL] as an API manufacturer' may be withheld." Vepuri relayed to Panchal the findings from the FDA's warning letter. The next month, the FDA issued an import alert that authorized the detention of all DRL-produced API imported into the United States. The import alert remained in effect until July 2012.

In May 2013 Vepuri authorized another purchase of the API manufactured by DRL. When the shipment arrived at the Philadelphia International Airport the next month, the FDA learned of the shipment and ordered it to be detained on the ground that KVK's ANDA did not list DRL as an approved API

3. Current Good Manufacturing Practices are regulations promulgated by the FDA that "address a variety of aspects of the drug manufacturing process, such as personnel, facilities, equipment, packaging, distribution, laboratory controls, and record keeping." Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC, 417 F. Supp. 3d 531, 537 (E.D. Pa. 2019).

manufacturer. The FDA ultimately refused import of the API into the United States.

On June 28, 2013, the FDA asked KVK to explain its attempt to import the API. Panchal responded via email:

> UCB has changed manufacturing site from [Belgium] to Mexico. CBE-30 Supplement to ANDAs have been submitted to FDA for approval. Upon approval of CBE-30 Supplement, process validation will be performed and one batch will be placed on long-term room temperature stability study.

A month after Panchal sent that email, he filed on KVK's behalf a Changes Being Effected in 30 Days Notice ("CBE-30"), which is a method of notifying the FDA of a prospective change to an approved drug that a manufacturer expects to implement within 30 days. See 21 C.F.R. § 314.70(c). In the CBE-30, Panchal asserted that KVK intended to use the API from DRL and would await the FDA's approval before further distributing the Hydroxyzine. He did not mention that KVK had already begun manufacturing the drug with the DRL-produced API. The FDA rejected the CBE-30, finding that it proposed a major change for which a more comprehensive application and approval process was needed.

In November and December 2013, the FDA inspected KVK's facilities in Newtown. Inspectors found photos in KVK's files showing containers of API labeled "Made in Mexico" and stamped with markings in Spanish. During the inspection, Panchal told

an FDA inspector that KVK had not received any prior shipments of the API produced by DRL. He also stated to the inspectors that he believed UCB had manufactured the detained API, that he did not know that UCB manufactured the API in Mexico, and that he would investigate the matter further. Sometime later, Panchal falsely advised inspectors that KVK had disclosed that the API was being manufactured at a new site in Mexico in its annual drug report.

On December 31, 2013, KVK through Vepuri and Panchal informed the FDA in writing that a former employee's "inappropriate regulatory evaluation" caused it to manufacture Hydroxyzine with the unapproved API. KVK's response further acknowledged that it should have investigated "whether or not previous batches had been received."

On January 6, 2014, KVK OPCO, Inc., a subsidiary of KVK, received a check in the mail from a customer in the amount of $185,437.42, of which $393.97 was for the purchase of the Hydroxyzine made from the DRL-produced API.

On June 27, 2014, Vepuri and Panchal met with representatives from the FDA. They continued to claim that a former employee had caused the company inadvertently to manufacture and distribute the Hydroxyzine with the DRL-produced API.

The FDA conducted more inspections of KVK's facilities in November and December 2014. On December 11, Panchal supplied to FDA inspectors a Manufacturing Deviations and Investigations Report. This report purported to detail KVK's investigation and conclusions concerning its use of DRL's API. Although Panchal was aware that Vepuri had ordered the API from DRL, the report stated it was "not clear why [UCB] shipped API manufactured in Mexico."

In March 2015, the FDA incorporated Vepuri and Panchal's false statements into a report on its investigation of KVK. The superseding indictment charges that Vepuri and Panchal knew the FDA's report contained inaccurate information based on the falsehoods they had provided to the FDA and that they failed to correct them.

III

Defendants have first moved to dismiss section 16(b)(1) of count one of the superseding indictment to the extent it charges them under 18 U.S.C. § 371[4] with conspiring to distribute a new drug in violation of 21 U.S.C. §§ 331(d) and 355(a). Section 331(d) prohibits the "introduction or delivery

4. Section 371 imposes criminal liability when "two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy."

for introduction into interstate commerce of any article in violation of section 344, 350d, 355, or 360bbb–3 of this title." Section 355(a) provides that "no person shall introduce . . . into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."

The Food, Drug, and Cosmetic Act ("FDCA") defines "new drug" as follows:

> (1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . . or
>
> (2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

21 U.S.C. § 321(p).

To distribute a drug lawfully that falls within the above definition, a drug manufacturer must submit to the FDA an Abbreviated New Drug Application ("ANDA"). The ANDA must include not only a "full statement of the [drug's] composition" but also "a full description of the methods used in, and the

facilities and controls used for, the manufacture, processing, and packing of such drug." § 355(b)(1)(A), (j)(2)(A)(vi).

The Government's theory of conspiracy liability under § 355(a) is that KVK's ANDA permitted it to manufacture Hydroxyzine using an API made only by UCB in its Belgian facility and by Cosma, S.p.A. in its Italian facility. KVK manufactured and distributed Hydroxyzine using an API sourced instead from DRL in Mexico. Because the Hydroxyzine was manufactured with API produced by DRL, it deviated from its approved ANDA and thus was a "new drug" within the meaning of § 355(a) for which KVK did not have FDA approval.

Defendants counter that their use of an API produced by DRL at the Mexican facility did not transform the Hydroxyzine which was subject to an approved ANDA into a "new drug" as defined under § 355. According to defendants, § 355 limits a new drug to be one which varies from its ANDA only in its composition, that is in its "chemical ingredients." Here, there was no difference in the chemical makeup of the drug with an API from Mexico from the chemical makeup of the drug with its API from Belgium and Italy. The only alleged difference was the place of manufacture of its API. The crucial question before the court is whether a deviation from an ANDA with respect to the place of manufacture of an API renders an approved drug a "new drug" proscribed by § 355(a).

Defendants' position finds statutory support. The FDCA defines "new drug" in § 321(p) by reference to its "composition": "Any drug . . . the composition of which is such that such drug is not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." (emphasis added). The court must assume that the phrase "new drug" in § 355(a) means the same thing as it does in § 321(p). See, e.g., Van Buren v. United States, 141 S. Ct. 1648, 1657 (2021).

The wording of the FDCA and its interpreting regulations further confirm that "composition" does not encompass a drug's manner or place of manufacture. Section 355(b)(1)(A) states that an ANDA must include:

> (i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use;
>
> (ii) a full list of the articles used as components of such drug;
>
> (iii) a full statement of the composition of such drug;
>
> (iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug.

In the above list, the "composition" of the drug is treated separately in subsection (iii) from subsection (iv) which concerns the "methods used in, and the facilities and controls

used for, the manufacture" of the drug. Reading "composition" to include "the place of manufacture" would render subsection (iv) superfluous.

Section 355's interpreting regulation, 21 C.F.R. § 314.50(d) mimics this distinction. The regulation sets forth the "technical sections" an ANDA must contain. Among other things, a drug manufacturer must include "[a] section describing the composition, manufacture, and specification" of the drug. § 314.50(d)(1). Again, the "composition" of a drug is distinguished from its manner or place of manufacture.

Another regulation, 21 C.F.R. § 310.3(h), contains a list of factors that describe the "newness of a drug." There is nothing stated about the manner or place of manufacture:

> (1) The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component.
>
> (2) The newness for a drug use of a combination of two or more substances, none of which is a new drug.
>
> (3) The newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug.
>
> (4) The newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used

> in another disease or to affect another structure or function of the body.
>
> (5) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

The text and structure of § 321(p) and § 355 as well as their interpreting regulations confirm that Congress intended "composition" to assume its ordinary meaning: "the qualitative and quantitative makeup of a chemical compound." Composition, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/composition. Indeed, "the definition of 'new drug' focuses on the drug's composition and use rather than on the process by which it was created." Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 395 (5th Cir. 2008).

Thus, for a drug with an approved ANDA, § 355(a) must be read, as defendants urge, to proscribe that drug only when it varies its chemical ingredients from its approved ANDA. The Government has not alleged that the Hydroxyzine that defendants introduced varied from its ANDA in its composition. Instead, it only faults the place where the API was manufactured.

As mentioned above, the Government's position is that any deviation from an ANDA in any respect renders a drug an unapproved new drug under § 355. Our Court of Appeals's

decision in United States v. Kaybel, Inc., 430 F.2d 1346 (3d Cir. 1970) casts serious doubt on that interpretation. There, the defendants were convicted under § 355 for repackaging and distributing a drug that otherwise complied in all respects with its ANDA. Our Court of Appeals reversed the conviction. The Court held that that the defendants did not by repackaging the drug transform it into a "new drug." In interpreting § 355, the Court declined to "characterize the product marketed by the appellants as a drug different from the 'new drug' for which approval already had been obtained or to construe the statute as requiring more than one application and approval for the same 'new drug.'" Id. at 1347.

At first blush, the repackaging in Kaybel seems like a minor deviation. Yet, § 355 requires an ANDA to contain "a full description of the methods used in, and the facilities and controls used for the manufacture, processing, and packing" of the drug. The text of § 355 draws no distinction between a drug's "packing" and its "manufacture" or "processing." As the Government is quick to point out, § 355 reflects the "congressional view that the way in which drugs are mixed and packaged is no less important than the chemical makeup of the drugs at issue." United States v. Baxter Healthcare Corp., 901 F.2d 1401, 1411 (7th Cir. 1990). Still, Kaybel rejects a

reading of § 355 that imposes criminal liability for every deviation in a drug from its otherwise effective ANDA.

The structure of § 355 also undermines the position that any deviation from an ANDA creates a new "new drug." Section 355(e) enumerates specific grounds when an "approval of an application with respect to any drug under this section" can be withdrawn or suspended. It requires the Secretary of Health and Human Services to withdraw an ANDA upon a finding "that the application contains any untrue statement of a material fact." § 355(e). In addition, the Secretary may withdraw an application based on changes to a drug's manufacturing process:

> on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

Id.

Congress adopted procedural protections for drug manufacturers. The Secretary may suspend an ANDA without notice but only upon a finding of "an imminent hazard to the public health" and provided that the Secretary gives the ANDA holder "prompt notice of his action" and "the opportunity for an

expedited hearing." § 355(e). Otherwise, to withdraw or suspend an ANDA for the above grounds, the Secretary of the Department of Health and Human Services must provide "due notice and opportunity for hearing to the applicant." § 355(e). In reviewing this language, the Supreme Court has concluded that the FDCA "did not provide any mechanism other than the [§ 355(e) procedure] whereby an NDA once effective could cease to be effective. Indeed [§ 355(e)] leads to the conclusion that an NDA remains effective unless it is suspended."[5] Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 633 (1973).

Section 355(e) is relevant to the court's analysis in two respects. First, § 355 reflects that Congress believed deviations from a drug's ANDA--at least with respect to its "manufacture, processing, and packing"--would be addressed through an administrative process replete with procedural safeguards. Second, § 355(e) offers an answer to the question of when and under what circumstances "an approval of an application . . . is effective," which is the precise language used in § 355(a). It is undisputed that at all relevant times, KVK has held an effective ANDA to distribute Hydroxyzine that has never been withdrawn or suspended.

5. An NDA or "New Drug Application" is the equivalent of an ANDA for an innovator, or non-generic, drug. The suspension authority under § 355(e) applies to NDAs and ANDAs alike.

The Government argues the FDCA should be construed liberally "consistent with the Act's overriding purpose to protect the public health." United States v. Article of Drug, Bacto-Unidisk, 394 U.S. 784, 798 (1969). However, the rule of lenity prevents the court from "interpret[ing] a federal criminal statute so as to increase the penalty that it places on an individual when such an interpretation can be based on no more than a guess as to what Congress intended." Ladner v. United States, 358 U.S. 169, 178 (1958). Undergirding this rule is the notion that "the citizen is entitled to fair notice of what sort of conduct may give rise to punishment." United States v. Ashurov, 726 F.3d 395, 402 (3d Cir. 2013) (quoting McNally v. United States, 483 U.S. 350, 375 (1987)). Even assuming that the relevant statute is ambiguous, the court must "apply the rule of lenity and resolve the ambiguity in [defendants'] favor." See United States v. Granderson, 511 U.S. 39, 54 (1994).

The Government raises the specter that if the court rules against it, public safety will be undermined. This is simply incorrect. Significantly, the superseding indictment does not charge that KVK manufactured or distributed an adulterated or misbranded drug.

With that said, the court readily acknowledges that the place of manufacture of a drug is critical. The court's

ruling will not deprive the FDA of its ability to remedy this type of noncompliance. The FDA has the authority to inspect and approve manufacturing facilities. See, e.g., 21 U.S.C. §§ 356a, 374. If current Good Manufacturing Practices are not followed or unsanitary conditions exist, the FDA can take appropriate action. See, e.g., § 351; 21 C.F.R. §§ 210.1 et seq. Criminal charges can be brought against those responsible for adulterated or misbranded drugs. See, e.g., §§ 331(a), 351, 352. Likewise, as explained above, the FDA can take administrative action under § 355(e) against those which distribute drugs contrary to what is stated in their approved ANDA about the place of the drug's manufacture.

The court must focus only on what the superseding indictment charges. Whatever wrongs the defendants may have committed, the allegations in the superseding indictment simply do not state the offense of conspiracy to violate § 355(a). This portion of the superseding indictment will be dismissed.

IV

Defendants have also moved to dismiss the conspiracy charge under 18 U.S.C. § 371 in count one of the superseding indictment to the extent it charges them in paragraph 16(a) with conspiring to defraud the United States by impeding, impairing, and defeating the lawful functions of the FDA to regulate drugs marketed and distributed in the United states and to make

misrepresentations to the FDA, and in paragraph 16(b)(2) with conspiring to make false statements and conceal information that FDA regulations required them to disclose, all in violation of 18 U.S.C. § 1001.[6] The superseding indictment alleges that KVK's use of the DRL-produced API constitutes a change in the conditions of its ANDA that rises to the level of "major manufacturing change." It charges defendants for violating regulations by not disclosing the change to the FDA and for making fraudulent misrepresentations to the FDA regarding the change.

The Government has alleged that 21 U.S.C. § 356a and its interpreting regulation, 21 C.F.R. § 314.70, imposed a duty on defendants to disclose the manufacturing changes. In

---

6. 18 U.S.C. § 1001 proscribes the following conduct:

> (a) . . . whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—
>
> > (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;
> >
> > (2) makes any materially false, fictitious, or fraudulent statement or representation; or
> >
> > (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry . . . .

addition to validating the effects of the change as it relates to the safety and effectiveness of the drug, § 356a requires an ANDA holder to disclose manufacturing changes to the FDA. See 21 U.S.C. § 356a(a).

The way the holder must notify the FDA depends on whether the change constitutes a "major manufacturing change." § 356a(a)(2). A major manufacturing change always requires the holder to submit a supplemental application before the changes are implemented. See § 356(c)(1). Section 356a(c)(2) defines "changes qualifying as major changes" as follows:

> a manufacturing change that is determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug.

Section 356's implementing regulations further defines a major change:[7]

> any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

21 C.F.R. 314.70(b) (emphasis added).

7. The disclosure requirements under 21 C.F.R. § 314.70 also apply to changes to an approved ANDA. 21 C.F.R. § 314.97.

Non-major changes, on the other hand, are changes that have less potential to adversely affect the drug. A "moderate change" is one that has a "moderate potential," while a minor change is one that has a "minimal potential." § 314.70(c)(1), (d)(1). A moderate change requires an ANDA holder to seek prior approval from the FDA by filing a Changes Being Effected in 30 Days Notice ("CBE-30"). By contrast, an ANDA holder may disclose a minor change retrospectively in the annual report it submits to the FDA. § 314.70(d)(1).

First, defendants argue that their manufacture of Hydroxyzine with the DRL API was not a manufacturing change and did not require FDA approval because DRL produced the API as UCB's subcontractor, and UCB retained control over the API's quality assurance. This argument fails at the motion to dismiss stage, however, because the superseding indictment alleges that DRL alone manufactured the API, and the court must accept as true this factual allegation. See Huet, 665 F.3d at 595-96.

Second, defendants assert that the FDA regulations were satisfied because UCB informed the FDA in its drug master file that it subcontracted manufacturing to DRL. As KVK's ANDA incorporated by reference UCB's drug master file, defendants contend the FDA had advanced notice of DRL's role in manufacturing the API KVK was using. This argument misunderstands the affirmative duty that 21 U.S.C. § 356a and

21 C.F.R. § 314.70 impose on an ANDA holder to report manufacturing changes. "[A] drug made with a major manufacturing change may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change." § 356a(c)(1) (emphasis added). Likewise, FDA regulations confirm "the applicant must notify FDA about each change in each condition established." § 314.70(a) (emphasis added). Each type of change must be reported in a specific manner: a "major" change requires a Prior Approval Supplement, a "moderate" change requires a Changes Being Effected in 30 Days Notice, and a "minor" change must be reported in an annual report. In all instances, § 314.70 requires the ANDA holder to report the change in a specific manner so as to alert the FDA to the change. Thus, regardless of whether information about the change found its way into UCB's drug master file, the superseding indictment properly alleges that KVK, as the ANDA holder, concealed information that § 314.70 required it and not someone else to disclose.

Third, defendants contend that the regulations governing whether prior notice to the FDA is required are impermissibly vague. They maintain that 21 C.F.R. § 314.70 does not provide fair warning of what constitutes a change in a "condition established" in an ANDA. They cite a 2015 FDA

guidance document in which the agency acknowledged confusion around what types of changes must be reported. They also argue that definitions of "major," "moderate," and "minor" change in 21 C.F.R. § 314.70 are impermissibly vague insofar as they do not provide fair warning of what form of notice must be provided to the FDA.

The Government first counters that the definitions of the severity of changes are not vague. Second, it argues the regulations required KVK to provide some notice regardless of the character of the change, and KVK provided none. Third, it contends the evidence will reflect KVK was aware that it was required to notify the FDA of the change.

A regulation is void for vagueness only if it "fails to provide people of ordinary intelligence a reasonable opportunity to understand what conduct it prohibits" or "authorizes or even encourages arbitrary and discriminatory enforcement." United States v. Gonzalez, 905 F.3d 165, 190–91 n.10 (3d Cir. 2008) (quoting Hill v. Colorado, 530 U.S. 703, 732 (2000)). "In criminal cases, because vagueness attacks are based on lack of notice, they may be overcome in any specific case where reasonable persons would know their conduct puts [them] at risk of punishment under the statute." United States v. Moyer, 674 F.3d 192, 211 (3d Cir. 2012) (internal citations omitted) (alteration in original).

The Supreme Court has made two observations relevant to defendants' vagueness challenge here. First, it has cautioned lower courts against applying a strict vagueness test to economic regulation:

> [E]conomic regulation is subject to a less strict vagueness test because its subject matter is often more narrow, and because businesses, which face economic demands to plan behavior carefully, can be expected to consult relevant legislation in advance of action [and may] clarify the meaning of the regulation by [their] own inquiry, or by resort to an administrative process.

Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 498 (1982) (footnotes omitted). Following this principle, our Court of Appeals has held that a regulation may not be void where it has a "narrow subject matter and reach," where those it affects are "sophisticated," and where those persons have "the ability . . . to obtain guidance" from regulators. United States v. Amirnazmi, 645 F.3d 564, 591 (3d Cir. 2011).

Second, the Supreme Court has acknowledged that "a scienter requirement may mitigate a law's vagueness, especially with respect to the adequacy of notice to the complainant that his conduct is proscribed." Hoffman Estates, 455 U.S. at 499. A statute that requires the Government prove beyond a reasonable doubt that a defendant willfully violated the law requires the jury to find the defendant knew the conduct was unlawful. See

Amirnazmi, 645 F.3d at 589–90. In such a circumstance, a defendant's "inability to appreciate the meaning of the law negatives the mens rea required for conviction." Id. at 589 (citation omitted).

The tenets from Hoffman Estates override defendants' vagueness arguments here. The regulations at issue are economic in nature. They apply only to generic drug manufacturers, a narrow and sophisticated segment of the population. Furthermore, defendants have been charged under a statute with a scienter requirement that vitiates vagueness concerns. The offenses charged in the superseding indictment have a "knowingly and willfully" mens rea component. 18 U.S.C. § 1001(a).[8] "Willfully," of course, requires a defendant know the

8. The general federal conspiracy statute, 18 U.S.C. § 371, may be violated two independent ways: "(1) conspiracy to commit a substantive offense proscribed by another statute (the '"offense" clause'); and (2) conspiracy to defraud the United States (the '"defraud" clause')." United States v. Alston, 77 F.3d 713, 718 (3d Cir. 1996). The superseding indictment charges defendants under both the offense clause and the defraud clause. When the fraud alleged under the defraud clause is entirely coextensive with the substantive offense charged under the offense clause, the Government must prove that the defendant possessed the mens rea required for conviction under the offense clause to secure a conviction under the defraud clause. See id. at 720–21. Because the charge of introducing an article in violation of §§ 331, 355(a) will be dismissed, the charge related to false statements and material concealments under 18 U.S.C. § 1001 is the only offense remaining under the offense clause. As § 1001 has a "knowingly and willfully" mens rea requirement, the Government must prove the same scienter to secure conviction under the defraud clause in this case.

unlawfulness of the alleged conduct. See, e.g., Amirnazmi, 645 at 589–90. Thus, Defendants can be convicted only if the jury finds beyond a reasonable doubt that they knew their conduct was unlawful--that is, they knew that the statements they made were false and the facts they concealed material. Defendants are free to argue their ignorance of the meaning of 21 U.S.C. § 356a and 21 C.F.R 314.70 to the jury. Id. at 589.

Any remaining concerns over the vagueness of these provisions can be addressed through jury instructions. Our Court of Appeals has recently issued guidance on prosecutions of ambiguous regulatory reporting violations: "to prove falsity beyond a reasonable doubt in this situation, the Government must prove either that its interpretation of the reporting requirement is the only objectively reasonable interpretation or that the defendant's statement was also false under the alternative, objectively reasonable interpretation." United States v. Harra, 985 F.3d 196, 204 (3d Cir. 2021). Consistent with Harra, defendants may dispute the Government's interpretation of these provisions, offer their own interpretation, and urge the jury to decide that any statements were not false and any concealments immaterial based on the competing interpretations.

KVK also argues that under the intra-corporate conspiracy doctrine it cannot be held liable for conspiring with

Vepuri and Panchal, its officers and employees. Whatever the rule may be in other Circuits, our Court of Appeals has held that individual officers and employees of a corporation can be guilty of conspiracy whether in the civil or criminal context. See Novotny v. Great Am. Fed. Sav. & Loan Ass'n, 584 F.2d 1235, 1256-1259 (3d Cir. 1978); United States v. Basroon, 38 F. App'x 772, 781 (3d Cir. 2002).

The question remains as to whether a corporation can engage in a criminal conspiracy with its officers and employees. While this Circuit has not specifically spoken on this issue, we agree with those decisions in other Circuits which have held that the intra-corporate company doctrine does not apply in a criminal case and that a corporation can be guilty of conspiracy with one or more of its employees. See, e.g., McAndrew v. Lockheed Martin Corp., 206 F.3d 1031, 1035-1041 (11th Cir. 2000); United States v. Hughes Aircraft Co., 20 F.3d 974, 979 (9th Cir. 1994). Furthermore, when officers or employees conspire as agents on behalf of a corporation as alleged herein, the corporation can be convicted of conspiracy. See United States v. Peters, 732 F.2d 1004, 1007-08 (1st Cir. 1984).

For all the above reasons, defendants' motion to dismiss count one to the extent it charges them under 18 U.S.C. § 371 and § 1001 will be denied.

V

KVK also has moved to dismiss Count Two of the superseding indictment, which charges it with mail fraud under 18 U.S.C. § 1341 and aiding and abetting under 18 U.S.C. § 2. To charge the offense of mail fraud, the Government must allege "(1) a scheme or artifice to defraud for the purpose of obtaining money or property and (2) use of the mails in furtherance of the scheme." United States v. Yusuf, 536 F.3d 178, 187 (3d Cir. 2008). A scheme to defraud may include a defendant's concealment of material facts. E.g., United States v. Bryant, 655 F.3d 232, 249 (3d Cir. 2011).

The superseding indictment alleges KVK intentionally defrauded a customer when it sold some of the Hydroxyzine made from the unapproved API:

> It was part of the scheme that defendant enriched itself by distributing the prescription drug, Hydroxyzine, manufactured using an API that was not a condition of the drug's FDA-approved Abbreviated New Drug Application (ANDA). In order to sell the drug to wholesalers and large retail pharmacies, including Customer 1 the defendant concealed that the drug as manufactured was not approved by the FDA and could not be lawfully distributed in interstate commerce.

It charges KVK in connection with a single payment of $393.97 on January 6, 2014, from a customer for the purchase of Hydroxyzine made from the unapproved API.

KVK urges this count be dismissed because the customer was not defrauded. KVK maintains it disclosed its use of the unapproved API when it issued a voluntary recall for the Hydroxyzine to its customers on December 9, 2013, more than three weeks before the customer sent its payment. KVK urges the court to take judicial notice of the recall letter it sent to its customers.

KVK's argument is without merit as it is grounded in information outside of the superseding indictment. Factual issues such as this must be resolved at trial. Again for purposes of a motion to dismiss, the court is limited to what the Government states in the charging document. See DeLaurentis, 230 F.3d at 661.